



Department of Animal and Range Sciences

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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket No. 99N-2151, 21 CFR Part 514 (New Animal Drug Applications; Sheep as a Minor Species)

I am commenting on Docket No. 99N-2151, "New Animal Drug Applications; Sheep as a Minor Species). The reclassification of sheep as a minor species with respect to all data requirements for new animal drug applications is in my opinion appropriate at this time.

The lack of approved drugs for use in sheep in the US is a major problem facing producers. Because of shrinking numbers, pharmaceutical companies are making a purely economical decision to not obtain clearance for use in sheep for many products. In short, the costs for some of the more burdensome data collection requirements are in many instances greater than projected profits from their use in sheep. This leaves the sheep producers in an extremely precarious position, especially when the pharmaceuticals are being readily utilized in other similar species or in sheep in other countries. The US sheep producer must compete with these other producers for his/her share of the marketplace.

From a health standpoint, producers must often opt for an older, less effective product (one that organisms have developed some resistance to) or in a number instances no treatment because none is available. The reclassification of sheep from a major species to minor species should encourage companies to pursue NADAs for sheep resulting in more effective therapeutic products labeled for sheep and a healthier sheep industry.

A handwritten signature in black ink that reads "Rodney Kott". The signature is fluid and cursive.

Rodney Kott, Ph.D.

Extension Sheep Specialist

99N-2151

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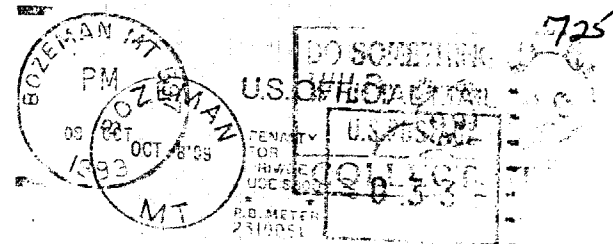
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